

VOLUME 2. ISSUE 3

Excellence in Military Medical Research

APRIL 2015

2015 Research and Innovation Month - Save the Dates



LT Ryan Kim Research Education Coordinator

3rd Annual Aware for All ■ 06 May 2015, 1100 – 1400, Building 19 Lobby

- Table display kick-off for 2015
 Research and Innovation Month
- Members of the WRNMMC and

National Capital Region - MD will showcase their research, hand out brochures, flyers, takeaways, and perhaps show video presentations and provide demonstrations

7th Annual National Capital Region MD Research Competitions

- 11 15 May 2015 Poster Display Week, Building 9 Lobby
- Interns, residents, fellows, clinicians, and other posters will be displayed in the Bldg. 9 lobby featuring their state-of-the art military medical research efforts.
- Participants are to display their posters starting at **noon** on **11 May 2015**.

■ 13 May 2015, 1300 – Poster Competitions (Judged Oral Presentations), Building 9 Lobby

- Case Report and Evidence Based Practice-Quality Improvement research competition finalists will present in front of their posters to a committee of walking judges.
- Award Ribbons will be pinned next to the poster winners for the Case Report and the Evidence-Based Practice Quality Improvement categories at 1800.
- 18 19 May 2015 Research Symposium I (0800 1245) and II (0800 1600), Memorial Auditorium (Building 19)
- Finalists for the Bailey K. Ashford and Robert A. Phillips research competitions will deliver slide presentations of their medical research with judges there, with awards handed out by BG Clark at 1500 on the **19 May 2015.**

30th Annual Navy-Wide Academic Research Competition, Clark Auditorium (Building 10)

- 26 May 2015, Clark Auditorium (Building 10)
- Winners of the Robert A. Phillips award will gather to compete at this event against other winners from San Diego, CA and Portsmouth, VA.

2015 Spring Research Summit

- 27 May 2015, Clark Auditorium (Building 10)
- Various Walter Reed National Military Medical research groups introduce their organizations via slide presentations (questions and answers are welcomed throughout the summit)



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Academic Research Education Office

7th Annual National Capital Region Research Competitions



LT Ryan Kim Research Education Coordinator

7th Annual National Capital Region Research Competitions

Many participants have been anxious to hear who the finalists are for their respective categories after abstracts were submitted in January 2015. After hours of careful review, the Department of Research Programs is pleased to announce the finalists for the 7th Annual National Capital Region Research Competitions listed below.

Congratulations to the finalists. The Walter Reed National Military Medical Center looks forward to your presentations at your respective events. Finalists for the Case Report and Evidence Based Practice – Quality Improvement categories will present their research at the Poster Competitions on 13 May 2015, in Building 9 Lobby. Finalists for the Bailey K. Ashford and the Robert A. Phillips categories will conduct a slide presentation of their research at Research Symposium I and II on 18 -19 May 2015, in the Memorial Auditorium. All winners will be granted their certificates at the end of Research Symposium II on 19 May 2015. In addition, winners of the Robert A. Phillips award will compete against the same category winners from San Diego, CA and Richmond, VA at the 30th Annual Navy-Wide Academic Research Competition coming up on 26 May 2015. The event will be held where it originated: at the Walter Reed National Military Medical Center in the Clark Auditorium.

Congratulations to the Finalists!

Case Report – Intern/Resident

- Lewis, William, MD Yellow Nail Syndrome
- Johnson, Jessica, MD A Case Series of Wounded Warriors Receiving Initial Fit PowerKnee Prothesis.
- Uwagbai, Omici, MD, MPH A Case of a 19 Year-Old Diagnosed with Granulomatosis with Polyangiitis
- Chern, Casey, MD Sweet's Syndrome Arising in a Scar
- Polfer, Elizabeth, MD <u>Turn-Up Plasty for Salvage of Transtibial Amputations</u>: An Illustrated Description of Surgical Technique
- Savioli, Stephen, MD <u>Kikuchi Disease</u>: A <u>Relieving Diagnosis for a Frightening Presentation</u>
- Winn, Aubrey, MD A Molluscum Contagiosum Look-Alike
- Wienandt, Nathan, DVM <u>Pyogranulomatous Pleuropneumonia in a Ferret (Mustela putorius furo) associated with Pseudomonas (Chryseomonas) luteola infection.</u>

Case Report – Fellow/Staff

- Fleming, Mark, DO Compassionate Care Case: ReCell Spray Skin in Combination with Split Skin Grafting.
- League-Pascual, James, MD, MS <u>A Case Report on the Use of Propranolol as a Successful Treatment for Pediatric</u> Venolymphatic Malformations (VLMs)
- Calais, Charles, DO, MS <u>Resolution of Alcohol-Induced Respiratory Reaction Following Aspirin Desensitization in AERD</u>
- Adams, Daniel, MD <u>Successful Treatment of Mycobacterium Abscessus Otitis Media with Tigecycline Salvage Therapy in a Pediatric Patient</u>.

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Evidence Based Practice – Quality Improvement

- Little, Dustin, MD <u>Implementation of New Chronic Kidney Disease Guidelines: A Quality Improvement Project.</u>
- Cohee, Brian, MD <u>Results of a Formal Mentorship Program for Internal Medicine Residents: Can We Facilitate Genuine Mentorship?</u>
- Ottolini, Katherine, MD <u>Reducing Unnecessary Radiation Exposure in Children Presenting to a Military Emergency Department with Head Injury.</u>
- Heinly, Alexander, RN <u>Patient Upward Mobility Program (PUMP)</u>: <u>Implementing an Early Mobilization Program in the Medical Intensive Care Unit (MICU)</u>
- LTJG Hausinger, RN Visual Cues to Increase Hand Hygiene Compliance
- Foster, Brian, DO The Effects of A-Flex on Auto-PAP Adherence and Efficacy
- Lawrence, Marguerite, DNP <u>An Assessment of Knowledge and Awareness of Cardiovascular Health Risk Factors</u> <u>Among Active Duty Service Members in a Joint Military Environment</u>
- Fiacco, Nicholas, MD <u>4+1 Ambulatory Clinic Block Scheduling: Improving the Internal Medicine Resident Continuity Clinic Experience</u>
- Cooper, Barbara, RN, MPA <u>Leveraging Technological Advances to Optimize Hemodialysis Adequacy While Decreasing Waste and Heparin and Normal Saline Use:</u>
- Kassop, David, MD <u>Effectiveness of a Standard Oral Beta-Blockade Strategy on Heart Rate Control in Patients Undergoing Coronary CT Angiography</u>.
- Cahill, Michael, MD <u>Implications of New Cholesterol Treatment Guidelines on Statin Utilization, Intensity, and Costs</u> in Active Duty Service Members
- Pierce, Shanon, CCRN <u>The MICU Spotlight Journal (MSJ)</u>
- Fleming, Mark, DO <u>DOD Orthopaedic Telemedicine/Teleconsultation Program</u>

Robert A. Phillips - Resident, Laboratory

- Pavey, Gabriel, MD <u>Targeted Stimulation of Retinoic Acid Receptor Signaling Mitigates the Formation of Heterotopic Ossification in an Established Blast-Related Traumatic Injury Model.</u>
- Packer, Kyle, MD Novel Anterior Chamber Tube Shunt with Tissue Autograft.

Robert A. Phillips - Fellow/Staff, Laboratory

- League-Pascual, James, MD, MS <u>Optimizing Central Nervous System (CNS) Penetration of Temozolomide After Intranasal Delivery (IN) in a Non-Human Primate Model: A Pharmacokinetic Comparison of Two Delivery Methods.</u>
- Mayer, Rulon, PhD Multimodality MRI to Detect Tumors.
- Biswas, Roopa, PhD Role of microRNAs in the Development of Prostate Cancer.
- Butts, Melissa, DO Characterization of Epitopes Identified with Cerebral Vasculature Injury.

Bailey K. Ashford – Laboratory

- Cox, Jeris, MD <u>Ulipristal Acetate Inhibits Extracellular Matrix Production in Human Leiomyomas in vivo</u>: A <u>Laboratory Analysis of a Randomized Placebo Controlled Trial</u>.
- Polfer, Elizabeth, MD <u>Development of a Rat Model for Blast-Related Post-Traumatic Heterotopic Ossification</u>.
- Vicente, Diego, MD <u>A Comparison of Uncontrolled Hemorrhage Models Using Cynomolgus Macaques vs. Yorkshire</u>
- Butts, Melissa, DO Characterization of Epitopes Identified with Cerebral Vasculature Injury.

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Robert A. Phillips – Resident, Clinical

- Shedlock, Katherine, MD Autism Spectrum Disorder Increases the Risk of Obesity and Metabolic Comorbidities.
- Hanley, Matthew, MD Risk Factors for Amputation in Combat Related Tibia Injuries.
- Nugent, James, MD, MPH <u>The Role of the Medical Home in Reducing Health Disparities Among Children with Special</u> Health Care Needs.
- Vlasov, Anton, DO The Efficacy of Two Trabecular Bypass Stents Compared to One.

Robert A. Phillips - Fellow/Staff, Clinical

- Hostler, David, MD, MPH Feasibility of Intercostal Artery Doppler Ultrasound Exam Prior to Thoracentesis.
- Little, Dustin, MD <u>Predictors of Non-Adherence in Kidney Transplant Patients Treated in a Federal Universal Healthcare System.</u>
- Nottingham, Elizabeth, BS <u>A Comparison of Feedback Strategies Provided in a Virtual Environment to Improve</u> Biomechanics of Service Members with Unilateral Transtibial Amputations.
- Singla, Manish, MD Topographical Mapping in a Cohort of Patients with Gastric Intestinal Metaplasia.

Bailey K. Ashford - Clinical

- Lucas, Donald, MD Assessing Readmission After General, Vascular, and Thoracic Surgery Using ACS-NSQIP.
- Sabino, Jennifer, MD Extremity Reconstruction in the War Wounded.
- Hostler, David, MD Feasibility of Intercostal Artery Doppler Ultrasound Exam Prior to Thoracentesis.
- Singla, Manish, MD <u>Topographical Mapping in a Cohort of Patients with Gastric Intentinal Metaplasia</u>.

Please check your emails or visit the Department of Research Program's Intranet website at

<u>http://www.wrnmmc.intranet.capmed.mil/EducationTrainingResearch/ResearchProgramsDepartment/SitePages/Home.aspx</u> for updates on this year's research competitions.

Further details will be announced as the events approach.

Please check the WRNMMC Intranet homepage and your emails for updates.

We look forward to everyone's participation!

Outstanding Accomplishments

BG Clark Recognizes and Award Research Trainees



During a recent Board of Director's Meeting,
Gen. Jeffrey B. Clark congratulated and presented the WRNMMC
Director's Medallion to the following medical trainees who
collaborated to present their original research at the American
College of Cardiology (ACC) Meeting in San Diego. At the ACC
Meeting, the ICHP was selected for the "Best Cardiovascular Team"
poster award for their poster about *Prediabetes reversal using a*novel comprehensive health model. Other trainees were recognized
by ACC for presenting the following abstracts as posters:

- 1. Michael Cahill; Rebecca Seifried; Julia Chernigal; Nicholas Fiacco; Patrick Moon; Michael Cheezum and Todd Villines. IMPLICATIONS OF NEW CHOLESTEROL TREATMENT GUIDELINES ON STATIN UTILIZATION, INTENSITY AND COSTS IN ACTIVE DUTY SERVICE MEMBERS. http://content.onlinejacc.org/article.aspx?articleid=2198764.
- Michael Donovan; Geoffrey Cole; Brynn Connor; Allen Taylor and Todd Villines. LONG-TERM MORTALITY IN THE PACC PROJECT COHORT: DOES CORONARY ARTERY CALCIUM HAVE ACTUARIAL SIGNIFICANCE IN THE YOUNG? http://content.onlinejacc.org/article.aspx?articleid=2198999.
- 3. Mariam Kashani; Arn Eliasson; Renata Engler; Ellen Turner; Nancy Tschiltz; Marilyn Grunewald; Joy Halsey; Todd Villines and Marina Vernalis. PREDIABETES REVERSAL USING A NOVEL COMPREHENSIVE HEALTH MODEL. http://content.onlinejacc.org/article.aspx?articleid=2198743





COL Peter Weina Presents the Letterman Lecture Series

COL Peter Weina, Chief of the Department of Research Programs at the Walter Reed National Military Medical Center and the 2014 winner of the Letterman Award for Medical Excellence, was invited by the National Museum of Civil War Medicine to speak at the Letterman Lecture Series. These events are presented by nominees and honorees of the Letterman Medical Excellence Award whose work has a significant impact on the future of medicine.

COL Weina's presentation *Infectious Diseases*, *Treatments*, and *Prevention Through American Military History* was held on 10APR2015 at the Clara Barton Missing Soldiers Office in Washington DC.

For more information, please visit the website at www.civilawrmed.org or contact April Dietrich at Letterman@civilarmed.org.



IRB Operations

Courtney Cox IRB Manager, IRB Operations Office

Investigational Device Exemptions (IDE)

The Investigational Device Exemptions (IDE) regulation (21 CFR 812) describes three types of device studies: significant risk (SR), nonsignificant risk (NSR), and exempt studies. Investigations covered under the IDE regulation are subject to differing levels of regulatory control depending upon the risk level of the device.

A. What is a Significant Risk Device Study?

Under 21 CFR 812.3(m), an SR device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- **B.** What is a Nonsignificant Risk Device Study?

An NSR device study is one that does not meet the definition for an SR device study.

C. Who Decides Whether A Device Study is SR or NSR?

Sponsors are responsible for making the initial risk determination and presenting it to the IRB. The Food and Drug Administration (FDA) is also available to help the sponsor, clinical investigator, and IRB in making the risk determination. Unless FDA has already made a risk determination for the study, the IRB must review the sponsor's SR or NSR determination for every investigational medical device study reviewed and modify the determination if the IRB disagrees with the sponsor.

- **D.** What are the Major Differences Between SR And NSR Device Studies?
 - 1. Significant Risk (SR) Device Studies
 - SR device studies must follow all the IDE regulations at 21 CFR 812.
 - SR device studies must have an IDE application approved by FDA before they may proceed.
 - 2. Nonsignificant Risk (NSR) Device Studies
 - NSR device studies must follow the abbreviated requirements at 21 CFR 812.2(b).
 - These abbreviated requirements address labeling, IRB approval, informed consent, monitoring, records, reports, and prohibition against promotion. However, there is no need to make progress reports or final reports to FDA.
 - NSR device studies do not have to have an IDE application approved by FDA.
- **E.** What are the IRB's responsibilities when it receives a device study for review?
 - IRBs should make the SR or NSR determination about a study by reviewing relevant information at a convened meeting. This information includes the description of the device, reports of prior investigations conducted with the device, the proposed investigational plan, and subject selection criteria.
- **F.** What should an IRB do for device studies that are exempt from the requirements of the IDE regulation (21 CFR 812.2(C))?

For studies that are exempt from the IDE regulations, the IRB does not need to decide whether the study poses a significant risk or nonsignificant risk. However, the IRB must still review the study in accordance with the IRB regulations before the investigation may begin.



Biomedical Research Laboratory Office





Molecular Biology Course

Last month, the BRL team opened the laboratory's doors once again for the Molecular Biology Lab Workshop. This year's course focused on gene expression analysis, specifically, teaching the students the principles behind and rudimentary steps of the polymerase chain reaction. The workshop was held on each of three successive Wednesdays. Each session involved a didactic portion and a lab practicum. Dr. Yaling Zhou, the BRL Scientific Director, led the organizational efforts. He, Dr. Danko and Dr.

Wendy Bernstein provided the lectures to the sixteen participants who included eight graduate medical education students (from Adult Infectious Diseases, Allergy & Immunology and General Surgery). Four individuals from the Naval Medical Research Center also participated in the workshop. The final session included a tour of the entire laboratory and offered the students a glimpse into the other capabilities of the lab. There was a high level of interest in this course offering, resulting in a wait list. The BRL study team is considering a second course this fall.







BRL Staff Picture



PFC Brandon Thompson Sumana Dey, PhD Franz A. Frye, PhD Brandi Benford, MS Yaling Zhou, PhD Cristina Caplinger, MS Brian Reinhardt, MS, MLS (ASCP) Robert Taylor, PhD Elena Morris CDR Janine Danko, MD, MPH, FACP SGT Robert A. Martinez





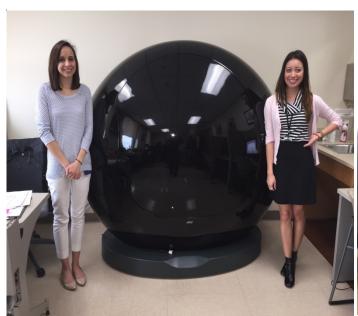
Investigative Research

Anmarie J. Widener, LCSW-C, Ph.D. Clinical Research Manager Defense & Veterans Brain Injury Center

DVBIC stands for the Defense and Veterans Brain Injury Center. This organization assists the DoD and VA in optimizing care of service members and veterans with traumatic brain injuries (TBIs) at home and in the deployed setting through four main pathways of care: state-of-the-art clinical care, innovative research, care coordination, and educational tools and resources.

DVBIC is a national program Headquartered in Silver Spring, MD; it has many sites throughout the U.S. and one site in Germany (see map on attached brochure). In providing education and resources to service members with some form of TBI and their families, DVBIC not only focuses on the SM's care and needs, but also their families, including children; for example, they provide information specifically written for a younger audience to increase understanding and resiliency of SM's families. See the attached brochure in appendix 1 and 2 for more details.

Stretched out (photo above) and take out/blur ID badge (photo below)



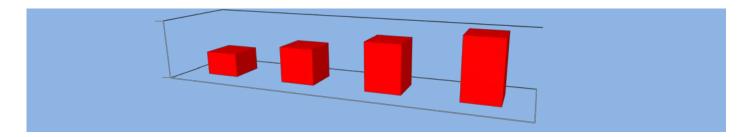


Laura Loyola and Angela Perta Brain Fitness Center at Walter Reed

The "ORRB" is optimized space designed to help individuals recover from stress and reach optimum levels of health and performance. The ORRB was designed by Lee McCormack. The Brain Fitness Center at Walter Reed Bethesda is researching the effectiveness of neuro and biofeedback treatment within the ORRB. The protocol, entitled "Biofeedback Treatment of mTBI Pathology Utilizing an Optimized Environment," will explore the effectiveness of the ORRB technology in treating mild Traumatic Brain Injury (mTBI) and/or Post-Traumatic Stress Disorder (PTSD). This study is currently recruiting patients with mTBI with or without PTSD. Study questions and participant referrals can be sent to Angela.M.Perta.ctr@mail.mil.

Biostatistician Office

Robin Howard, MA Biostatistician



Updates on Journal Requirements

1. We want to highlight another reason to produce a well-written protocol: Journals are starting to request copies of protocols from the corresponding author, which may be published online and linked with your manuscript. For example,

"The protocols of a clinical trial should be submitted as a separate PDF file, independent of the Supplementary Appendix. A statistical analysis plan may be included with the protocol, in the same PDF document." --- From the New England Journal of Medicine Author Center

You cannot change your original approved protocol when it is submitted to support a manuscript. Thousands of your peers will be able to compare the study procedures you published in your journal article with the study design you described in the protocol. Did you present all the outcomes you mentioned in the protocol? Did you follow up with subjects at all of the time points you had planned? Did you reach your required sample size? And when your protocol is published for all of the world to read, you may be thankful that 4 years ago, your DRP, scientific and IRB reviewers made those corrections to the document.

2. In 2014, this email was sent from a journal to all authors following submission of a manuscript (titles and names have been changed):

"After checking manuscript 12345 titled "XXX-YYY-ZZZ," we found that its title is similar to the abstract published at the following link: http://www.abstractsonline.com/...

... we have concerns regarding the authorship of the manuscripts as Drs. ABC and DEF are not listed as coauthors of manuscript 12345. I look forward to receiving your clarification within the coming 2 days."

Journals may now compare the list of authors on your manuscript with the authors listed on the abstract/poster you submitted 3 years ago. Choose your coauthors wisely. Given the frequent transfers and deployments among our military personnel, be diligent about maintaining contact information with your coauthors. Here is one guideline for authorship:

 $\frac{http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html}{\\$

Despite the ever-growing list of requirements from reviewers and journals, WRNMMC investigators continue to publish high quality research results: a small sample of the hundreds of articles published each year are listed at the end of this newsletter. DRP recognizes the increasing obstacles facing investigators in the planning, conducting, and publishing of their research, and we offer our assistance throughout the process.

Business Office



Lisa Potts Business Cell

Grant Writing Guidance

On January 22, 2015, BG Clark was the invited guest speaker at the Department of Research Programs (DRP) retreat. One major point he briefed the group on was Walter Reed National Military Medical Center (WRNMMC) hospital being considered as THE flagship hospital within the Department of Defense as per our mission statement. As a premier clinical organization, WRNMMC represents a clinical and scientific knowledge base which is primed for innovative research. A DRP milestone has been reached within

the Business Office which now allows WRNMMC to facilitate the grant submission process for our investigators by offering assistance to investigators in grant writing, administration, submission and award processes. The DRP Business Office offers the services of a Grants Writer who is tasked with increasing the grants awards to WRNMMC by providing support to investigators in locating funding opportunities, interpreting grant opportunity guidelines and assisting with submission.

The DRP grants infrastructure has made swift progression in establishing a system for submitting extramural grant applications directly from WRNMMC to funding agencies and sponsors. In the past, investigators have utilized the services of our foundation partners. While we do not prohibit investigators from continuing to work with our foundation partners, we invite you to engage the services of the DRP Business Office Grant Writer for review of the grants instruction and assistance with required grant submission processes. The Grants Writer is also available to provide electronic submission through the many sponsor electronic submission systems on behalf of the WRNMMC.

Any funding provided through the WRNMMC Graduate Medical Education programs are considered intramural funding. For intramural funding, investigators are required to complete the Application for Intramural Funding form and submit the form to LCDR Ruben Acosta at ruben.d.acosta.mil@mail.mil or Mr. Steve Ross at steven.d.ross1.civ@mail.mil. Please be advised that Intramural funding is limited to \$7,500 per year for a maximum of 2 years. This means that only \$15,000 is available for a single research study for a 2 year project. Extensions may be requested for projects which may potentially run past the 2 year maximum. Those extensions shall be reviewed and granted on a case by case basis and awarded after determination of merit. Unfortunately, intramural funding may not be used to support travel expenses.

The DRP Business Office and the Grants Writer look forward to supporting and working closely with our investigators as we continue to move forward with the establishment of WRNMMC as a leading DoD research institution. Please visit the DRP website to review funding opportunities or contact the Grants Writer, Lisa Potts, at lisa.m.potts6.ctr@mail.mil.



IRB Operations Office



Lorna Moore Clinical Trials Auditor Research Compliance Officer

Reportable Events in Research (AEs and UPIRTSO) Part I

What is an adverse event (AEs)?

Adverse Event is any untoward or unfavorable medical occurrence in a human subject participating in a clinical trial (e.g. a subject reporting a headache).

There are various types of Adverse Events which are as follows:

A **Related Adverse Event** is an event in which there is a reasonable possibility the incident, experience or outcome may have been caused by the procedures, the investigational drug or device used in the research (e.g. redness and swelling at an injection site).

An Unrelated Adverse Event is an event where there is no reasonable correlation to attribute the adverse event to the research study (e.g. a fall resulting from slipping on an icy sidewalk).

An Expected Adverse Event is an event that is expected and is listed in the investigator brochure, protocol and informed consent, investigational product insert package or device insert package (e.g. diarrhea, nausea, fatigue, pruritus).

An Unexpected Event is an event in which the nature, severity or frequency of the AE is not consistent with any of the following: IB, investigational plan or application, IRB approved protocol, IRB approved informed consent, labeling and package inserts, HIPAA authorization document or the reasonable expected natural history and progression of the underlying condition or disease of the subject (e.g. liver failure due to diffuse hepatic necrosis occurring in a subject without any underlying liver disease).

An Unanticipated Problem (UP) Involving Risks to Subjects or Others (UPIRTSO) is an event/problem that was not previously known and potentially increased the likelihood of harm to subject or others. Think of:

Fred Fatal
Doesn't Disability
Have Hospitalization
Any Anomaly
Money Medically Significant

Remember

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Adverse events, including events not related to or caused by the subject's study participation, should be collected, reviewed and tracked by the investigator. Events which are to be reported should be defined in the protocol for both routine and unexpected events. Adverse Events that have been described in the protocol, IC, IB, package inserts and <u>are not related</u> to subject participation in the study or <u>do not meet the prompt reporting criteria</u> can be reported in the studies Continuing Review Report. Reporting criteria can be found in the WRNMMC IRB Handbook.

Life Threatening

At WRNMMC, before drafting a research consent form, please log onto IRBNet (http://fhpr.dhhq.health.mil/dmrn.aspx) – you must have a CAC; go to "Forms and Templates;" and select the Library "WRNMMC Department of Research Programs (DRP) – Documents for Researchers." This Library contains the "Consent Form and HIPAA Authorization" template, as well as other research-related templates, forms, instructions, guidebooks, handbooks (Chapter 5 of the WRNMMC IRB Handbook provides details on the consent form and the informed consent process), and general information.

Monthly Research Roundtable



Lisa Thompson, MHA, MBA, Supervisory Medical Education Specialist Department of Research Programs

On 24 March 2015, Ms. Lisa Thompson, the new Supervisory Medical Education Specialist, hosted the Department of Research Programs' monthly Research Roundtable. This event allows researchers to gather and discuss Federal and State laws, rules and regulations; institutional policies and procedures; and other topics that affect their research protocol submissions, clinical research studies and publication clearance.



LCDR Acosta addressed the audience concerns about the expiring IRBNet contract. He announced that the contract with IRBNet has been extended for six months. This means, investigators would still be able to use IRBNet until 29 September 2015. During that time frame, the contract has been put up for a rebid. A new vendor would be determined on the 1st of April 2015.





Moving forward, DRP will be inviting participants to offer requests for topics to be included and members from each of DRP's sections will be providing representatives to discuss hot topics related to their sections.



Research Roundtable Featured Topic of Discussion

Lisa Thompson, MHA, MBA, Host of Research Roundtable

Section 5.5.5 in the DRP Protocol Template

Written by Deborah Kessler, RN, MSN

The current WRNMMC DRP protocol template includes a new section 5.5.5 titled "Data Collection." Part A is for the description of how data will be collected from study participants. In this part the

research team describes the questionnaires and data collection tools that will be administered to the study participants, and how and when they will be administered. If there is a sponsor or master protocol, the research team can refer back to that document (e.g. see sponsor protocol sections 6.3-6.6) if it has some part or all of the requested information. If your study is a retrospective chart review, the answer to part A is "not applicable." All data collection will be from already existing records; you will not be collecting any data directly from study participants.

Part B, where the research team needs to answer questions about the source and type of data collected from existing data sources in the military healthcare system (MHS), seems to be the part of the new 5.5.5 that raises the most questions from researchers. It was written by the Defense Health Agency (DHA) and is adapted from information that has been required in the past by TRICARE for research using their data. These Part B questions are originally designed to get information from people who wanted to do research with "big data" – the data that DHA and TRICARE have from across the military health care system (MHCS) and all MHCS beneficiaries. Most researchers here at WRNMMC are dealing with "little data" – the data on their subjects in the local data systems such as AHLTA, Essentris, or CHCS.

For most researchers here, the answer to 5.5.5. b.i. will be "no" – few researchers here will have a data consult with a data expert. This is really aimed at people who want to do a query across multiple data systems to answer some question or explore some relationship. In ii. the research team is asked to indicate whether they are receiving a data extract or accessing a data system. If you are asking IT to query a system for you and provide you with data, you are receiving a data extract. If members of the research team will be going into systems such as AHLTA or CHCS to look up records and record data, you are requesting access to those MHS systems. If all the data will be obtained directly from study participants, then nothing is checked here – it can be left blank or "NA" typed in. Then you are asked in iii. if you will be using only de-identified data in your study. If your study has a master list or master code, you do not have de-identified data but coded data and the answer to iii. is "no."

If your research deals with health information that you will obtain from MHS systems, the answer to iv. is "yes." Most research done here does involve health information. The next question in v. is if researchers will be accessing a system to obtain personally identifiable information that is not connected with health information. The answer to this is usually "no," but if you're doing a study with staff members that is not about healthcare and accessing a system such as email rosters to get a list of possible participants, the answer here would be "yes."

The table in vi. is similar to the table in the previous protocol template that asked researchers to identify the HIPAA identifiers they will collect from study participants. The main difference from the previous table is that now the research team must identify the source of the identifiers they are collecting (whether each one is being collected from the study participant, a MHS system, or

from some other source). Some identifiers may be collected from more than one source – for example, dates may be collected from both the study participant (he is asked to provide his date of birth) and from MHS (the research team gets dates of procedures from the participant's AHLTA records). This table also includes rank as a unique identifier. If a research subject is asked for their specific rank (e.g. O-4 or E-2) this is a unique identifier.

If a research subject is asked to indicate if they fall within a rank range (e.g. O-1 to O-3 or E-5 to E-8), it does not count as collecting rank as a unique identifier. Please note that in the MHS, individual's social security numbers are frequently used as medical record numbers – if you are collecting medical record numbers, you are probably collecting either a study participant's social security number (SSN) or their sponsor's SSN as well.

Even if you are only collecting the last four digits of someone's SSN, it is the same as collecting their whole SSN for the purposes of this table.

In vii. the research team must identify the systems they will access within MHS to obtain data. There are many systems, most of which few researchers here access. The best I can say is if you don't recognize the acronym, you aren't using that system. In the next question you must indicate whether or not you are merging data with data from sources outside MHS. The answer to this is usually "no." One example of "yes" would be collecting MHS data and data from a subject's military unit (e.g. PT scores) and then merging that data.

The research team states in x. whether or not there is a reasonable possibility the data collected will become identifiable. The research team must look at their subject population, the data collected, and the study's security/confidentiality procedures and determine what the proper answer for their study is. There is no one right answer that applies to every study.

Finally, the research team must provide justification for collecting the SSN of study participants. A common justification is that this is needed to ensure the research team accesses the correct records in MHS systems such as AHLTA and CHCS.

If you have questions about how to answer something in this section, please call DRP and we will help you find the right answer for your study's particular circumstances.

Invitation to Research Roundtables

DRP invites participants to offer requests for topics of discussion. DRP's representatives are invited to provide representatives to discuss hot topics related to their sections and participants needs.

We invite you to join us for our next Roundtable on 21 April 2015, 1200-1300, in the America Building (Bldg. 19), Room 2301, Desert Conference Room.

Ms. Lisa Thompson, Supervisory Medical Education Specialist, will be hosting the Research Roundtable. If you would like to block an allotted period of time to present a topic for discussion with questions and answers, please send us your RSVP. We will place you on the agenda. Speakers will receive an agenda listing their topics of discussion prior to the meeting. Also, an agenda will be provided to all attendees during the Roundtable. Please email Mr. John Fadoju at john.o.fadoju.ctr@mail.mil or Ms. Lisa Thompson at lisa.p.thompson5.civ@mail.mil with any topics you would like discussed.

Please note the reserved dates for Room 2301 through September 2015:

Research Roundtable Schedule
America Building (Bldg. 19), 2 Floor, the Desert Conference Room 2301

Tuesday, April 21, 1200-1300

CANCELLED – Tuesday, May 19, 1200-1300

CANCELLED - Tuesday, May 26, 1200-1300

Tuesday, May 12, 1200-1300

Tuesday, June 23, 1200-1300

Tuesday, July 21, 1200-1300

Tuesday, August 18, 1200-1300

Tuesday, September 22, 1200-1300



Monthly Meeting

Highlights

- New DRP Medical Education Assistant Mr. John Fadoju introduced.
- LCDR Acosta discussed the IRBNet contract and Share Point.
- Several DRP employees were recognized for their perseverance in gaining support producing the new Bailey K.
 Ashford and Robert A. Phillips Medallions that will be presented to the finalist of Symposium II during the 2015
 Research and Innovation Month.

Mr. John Fadoju



John Fadoju is a native of Nigeria who has lived in Woodbridge, Virginia since 2005. He graduated from George Mason University in 2014 with a Bachelor of Science degree in Chemistry. Mr. Fadoju transitioned to working as a Medical Support Assistant for the Post Anesthesia Care Unit at the Walter Reed National Military Medical Center. Now, Mr. Fadoju works as the Medical Education Assistant for the Department of Research Programs.

Mr. Fadoju started working as a Department of Research Programs Contractor in March 2015. Currently he works with Ms. Thompson and LT Kim to set up events for the 2015 Research and Innovation Month. Mr. Fadoju hopes to have a great learning experience while looking forward to utilizing his talents to leverage and market Academic Research Medical Education.

Publications Clearance Office



MAJ Scott Baumgartner Determination Official

Publication Clearance Frequently Asked Questions

Question: What types of things need to be submitted for publication clearance?

Answer: Any oral or written authored academic work submitted for public release in which the author represents him/herself as a member of WRNMMC or discusses WRNMMC beneficiaries. Authored academic work refers to any written document or oral presentation to include, but not limited to, abstracts, manuscripts, case reports, book chapters, letters to

the editor, speeches, and didactic presentations. Furthermore, "public" refers to any entity outside of the Department of Defense (DOD) to include DOD sponsored events/publications open to the public.

Question: I submitted my abstract for clearance, and it was accepted. Do I need to submit anything else?

Answer: Yes. Your abstract is not cleared in lieu of your final document (i.e. manuscript, poster, etc). If your abstract is accepted, you must then submit your final product for clearance as well. Submit it as a new package under the original submission.

Publications Clearance Office

Question: How do I obtain publication clearance?

Answer: You must submit your project into IRBNet which is a web-based electronic submission tool. This is the same system through which research projects are submitted for review. Once your project is submitted into IRBNet, it is routed to the appropriate department for clearance (e.g. PAO).

Question: I put my project into IRBNet. Does that mean my publication Clearance request goes to the IRB for approval?

Answer: No. The Institutional Review Board (IRB) is a group of individuals that represents the institution and is responsible for review of the safety and ethics of a research study involving human subjects as outline by the code of federal regulations. They do not review your publication clearance request. Your request for publication clearance is, however, submitted via IRBNet. IRBNet is an web based electronic submission tool which is also used to submit research studies for review and approval by the IRB.

Publications Clearance

(Provided by the Darnall Medical Library) WRNMMC authors are in bold.

March 2015 PubMed Citations

- 1. Ahmadi A, Leipsic J, Feuchtner G, et al. Is metabolic syndrome predictive of prevalence, extent, and risk of coronary artery disease beyond its components? Results from the multinational coronary CT angiography evaluation for clinical outcome: an international multicenter registry (CONFIRM). *PLoS One*. 2015;10(3):e0118998. WRNMMC Author: Villines TC
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- 3. Bateman NW, Jaworski E, Ao W, et al. Elevated AKAP12 in paclitaxel-resistant serous ovarian cancer cells is prognostic and predictive of poor survival in patients. *J Proteome Res*. 2015 Mar 19. [Epub ahead of print] WRNMM Authors: **Dubil E, Marcus C, Phippen NT, Hamilton CA**
- 4. **Brietzke SE, Pusz MD**. An anatomically based analysis of objectively measured pediatric snoring: a pilot study. *Otolaryngol Head Neck Surg*. 2015;152(3):561-6.
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- 7. **Carter C**, Reid T, Fisher G, et al. O3.8 Early Results: "ROCKET" a phase II Study of RRx-001, a novel triple epigenetic inhibitor, Resensitization to Irinotecan in Colorectal Cancer. *Ann Oncol*. 2015;26(suppl 2):ii4-ii5.
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- 10. Devine K, Connell MT, Richter KS, et al. Single vitrified blastocyst transfer maximizes liveborn children per embryo while minimizing preterm birth. *Fertil Steril*. 2015. pii: S0015-0282(15)00162-4. WRNMMC Authors: **Ramirez CI**
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- Ellsworth RE, Mamula KA, Costantino NS, et al. Abundance and distribution of polychlorinated biphenyls (PCBs) in breast tissue. *Environ Res*. 2015;138C:291-297.
 Additional WRNMMC Author: Shriver CD
- 13. Engler RJ, Nelson MR, Collins LC Jr, et al. A prospective study of the incidence of myocarditis/pericarditis and new onset cardiac symptoms following smallpox and influenza vaccination. PLoS One. 2015;10(3):e0118283. Additional WRNMMC Authors: Spooner C, Hemann BA, Gibbs BT, Atwood JE, Howard RS, Chang AS, Vernalis MN
- 14. **Fagen KE**, Shalaby-Rana E, Jackson AM. Frequency of skeletal injuries in children with inflicted burns. *Pediatr Radiol*. 2015;45(3):396-401.
- 15. Gawrys B, **Mullenix P**, **Nicastri DG**. Hemothorax after delayed fracture of sternal wire. *Ann Thorac Surg*. 2015;99(3):1086.
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- 19. **Green JM 3rd, Sabino J, Fleming M, Valerio I**. Intraoperative fluorescence angiography: a review of applications and outcomes in war-related trauma. *Mil Med*. 2015;180(3 Suppl):37-43.
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- 23. **Hulten E**, Ahmadi A, Blankstein R. CT assessment of myocardial perfusion and fractional flow reserve. *Prog Cardiovasc Dis.* 2015. pii: S0033-0620(15)00015-8.
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Appendix 1 – Defense and Veterans Brain Injury Center

Traumatic Brain Injury (TBI)

What Is TBI?

- A blow or jolt to the head that disrupts the function of the brain
- Not all blows or jolts to the head result in a TBI
- Severity of the TBI is determined at the time of injury and may be classified as:
 - mild
 - o moderate
 - o severe
 - penetrating

Common Causes of TBI in the Military

Blast exposures
Bullets or fragments
Falls
Motor vehicle accides

Motor vehicle accidents Other (blunt objects)

Common Symptoms of Mild TBI

Physical

Headache

Sleep disturbances

Dizziness

Balance problems

Nausea/vomiting

Fatigue

Visual disturbances

Light sensitivity

Ringing in ears

Cognitive (Thinking)

Slowed thinking
Poor concentration
Memory problems

Difficulty finding words

Emotional

Anxiety Depression Irritability Mood swings

Mild TBI/Concussion

Did you know?

- Concussion is another word for a mild TBI (mTBI).
- Concussion is the most common form of TBI in the military population.
- Concussion results from a head injury that briefly knocks you out or makes you feel dazed, confused or "see stars."

After concussion

- · Symptoms typically improve within hours to days and resolve within weeks.
- The term mild TBI describes the injury, not necessarily the number or severity of symptoms.
- Even if you've had more than one concussion, full recovery is expected.
 - Each time you sustain an additional concussion, your recovery may take longer.

Help Yourself Recover More Quickly

Report the incident

Protect yourself and/or your unit.

Get checked out

· Be honest with your provider about any symptoms.

Rest

- Avoid physical exertion (heavy lifting, exercising, etc.).
- Avoid mental exertion (writing reports, activities requiring intense concentration, etc.).

Return to duty

- Most people can expect to recover fully and return to duty.
- Your health provider will determine when it's safe for you to return to duty.



Resource for Moderate and Severe TBI

Traumatic Brain Injury: A Guide for Caregivers of Service Members and Veterans

Module 1: Introduction to TBI

Module 2: Understanding Effects of TBI and What You Can Do to Help

Module 3: Becoming a Family Caregiver

for a Service Member/Veteran with TBI

Module 4: Navigating Services and Benefits

To download, visit www.DVBIC.org



Living with a traumatic brain injury or know someone who is?

Visit BrainLineMilitary.org to find resources about traumatic brain injury for service members, veterans, National Guard, Reserve and family members.

To learn more about TBI, visit www.DVBIC.org



Appendix 2 – Defense and Veterans Brain Injury Center

DEFENSE AND VETERANS BRAIN INJURY CENTER



Defense and Veterans Brain Injury Center (DVBIC) assists the DoD and VA in optimizing care of service members and veterans with traumatic brain injuries (TBIs) at home and in the deployed setting, through state-of-the-art clinical care, innovative research, care coordination, and educational tools and resources.



How We Serve

Care Coordination

- Connects service members with a TBI sustained during Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF) or Operation New Dawn (OND) to health care and resources
- Follows service members for two years or until symptoms resolve
- Assists service members during transitions from DoD to VA and civilian life

Education

- Provides educational materials on awareness, prevention, diagnosis, treatment and management of TBI
- Provides education and training for health care providers, military leadership, service members, veterans, families and civilian communities

Protecting Service Members

- Offers in-theater support to medical providers through training resources and email consultation
- · Collects and analyzes data that enhance TBI care and treatment

Clinical Care

 Provides assistance at medical sites for TBI-related evaluation, diagnosis, treatment and follow-up care

Research

· Conducts research to better understand, assess, prevent and treat TBI

DVBIC Network

DVBIC Headquarters

Silver Spring, MD

Military Medical Centers

- Walter Reed National Military Medical Center, MD
- San Antonio Military Medical Center, TX
- NMC San Diego, CA
- Camp Lejeune, NC
- Camp Pendleton, CA
- · Fort Belvoir, VA
- · Fort Bragg, NC
- · Fort Carson, CO
- · Fort Hood, TX
- Joint Base Elmendorf-Richardson, AK
- Landstuhl Regional Medical Center, Germany

Veterans Affairs Hospitals

- Richmond, VA
- Tampa, FL
- · Minneapolis, MN
- · Palo Alto, CA
- Boston, MA



For more information: www.DVBIC.org

Feedback on the Newsletter

Please send feedback on the newsletter to:

dha. be the sda. ncr-medical. list. wrnm-drp-new sletter-feedback@mail.mil

